

(2) If applicable, it has obtained the State certification required under paragraph (b) of this section.

**§ 422.402 Federal preemption of State law.**

The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to the MA plans that are offered by MA organizations.

[70 FR 4733, Jan. 28, 2005]

**§ 422.404 State premium taxes prohibited.**

(a) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, or any of their political subdivisions or other governmental authorities with respect to any payment CMS makes on behalf of MA enrollees under subpart G of this part, or with respect to any payment made to MA plans by beneficiaries, or payment to MA plans by a third party on a beneficiary's behalf.

(b) *Construction.* Nothing in this section shall be construed to exempt any MA organization from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

[63 FR 35099, June 26, 1998, as amended at 70 FR 4733, Jan. 28, 2005]

**Subpart J—Special Rules for MA Regional Plans**

SOURCE: 70 FR 4733, Jan. 28, 2005, unless otherwise noted.

**§ 422.451 Moratorium on new local preferred provider organization plans.**

CMS will not approve the offering of a local preferred provider organization plan during 2006 or 2007 in a service area unless the MA organization seeking to offer the plan was offering a local preferred provider organization

plan in the service area before December 31, 2005.

**§ 422.455 Special rules for MA Regional Plans.**

(a) *Coverage of entire MA region.* The service area for an MA regional plan will consist of an entire MA region established under paragraph (b) of this section, and an MA region may not be segmented as described in § 422.262(c)(2).

(b) *Establishment of MA regions—(1) MA region.* The term “MA region” means a region within the 50 States and the District of Columbia as established by CMS under this section.

(2) *Establishment—(i) Initial establishment.* By January 1, 2005, CMS will establish and publish the MA regions.

(ii) *Periodic review and revision of service areas.* CMS may periodically review MA regions and may revise the regions if it determines the revision to be appropriate.

(3) *Requirements for MA regions.* CMS will establish, and may revise, MA regions in a manner consistent with the following:

(i) *Number of regions.* There will be no fewer than 10 regions, and no more than 50 regions.

(ii) *Maximizing availability of plans.* The main purpose of the regions is to maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, or geographic location, especially those residing in rural areas.

(4) *Market survey and analysis.* Before establishing MA regions, CMS will conduct a market survey and analysis, including an examination of current insurance markets, to assist CMS in determining how the regions should be established.

(c) *National plan.* An MA regional plan can be offered in more than one MA region (including all regions).

**§ 422.458 Risk sharing with regional MA organizations for 2006 and 2007.**

(a) *Terminology.* For purposes of this section—

*Allowable costs* means, with respect to an MA regional plan offered by an organization for a year, the total amount of costs that the organization incurred in providing benefits covered under the

original Medicare fee-for-service program option for all enrollees under the plan in the region in the year and in providing rebatable integrated benefits, as defined in this paragraph, reduced by the portion of those costs attributable to administrative expenses incurred in providing these benefits.

*Rebatable integrated benefits* means those non-drug supplemental benefits that are funded through beneficiary rebates (described at § 422.266(b)(1)) and that CMS determines are additional health benefits not covered under the original Medicare program option and that require expenditures by the plan. For purposes of the calculation of risk corridors, these are the only supplemental benefits that count toward allowable costs.

*Target amount* means, with respect to an MA regional plan offered by an organization in a year, the total amount of payments made to the organization for enrollees in the plan for the year (which includes payments attributable to benefits under the original Medicare fee-for-service program option as defined in § 422.100(c)(1), the total of the MA monthly basic beneficiary premium collectable for those enrollees for the year, and the total amount of rebatable integrated benefits), reduced by the amount of administrative expenses assumed in the portion of the bid attributable to benefits under original Medicare fee-for-service program option or to rebatable integrated benefits.

(b) *Application of risk corridors for benefits covered under original fee-for-service Medicare*—(1) *General rule.* This section will only apply to MA regional plans offered during 2006 or 2007.

(2) *Notification of allowable costs under the plan.* In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization must notify CMS, before that date in the succeeding year as CMS specifies, of—

(i) Its total amount of costs that the organization

incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan (as described in paragraph (a) of this section).

(ii) Its total amount of costs that the organization incurred in providing rebatable integrated benefits for all enrollees under the plan (as described in paragraph (a) of this section), and, with respect to those benefits, the portion of those costs that is attributable to administrative expenses that is in addition to the administrative expense incurred in provision of benefits under the original Medicare fee-for-service program option.

(c) *Adjustment of payment*—(1) *No adjustment if allowable costs within 3 percent of target amount.* If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan and year, there will be no payment adjustment under this section for the plan and year.

(2) *Increase in payment if allowable costs above 103 percent of target amount*—

(i) *Costs between 103 and 108 percent of target amount.* If the allowable costs for the plan for the year are greater than 103 percent, but not greater than 108 percent, of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount equal to 50 percent of the difference between those allowable costs and 103 percent of that target amount.

(ii) *Costs above 108 percent of target amount.* If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) of the Act by an amount equal to the sum of—

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between those allowable costs and 108 percent of that target amount.

(3) *Reduction in payment if allowable costs below 97 percent of target amount*—

(i) *Costs between 92 and 97 percent of target amount.* If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, CMS will reduce the

total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and those allowable costs.

(ii) *Costs below 92 percent of target amount.* If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to the sum of-

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between 92 percent of that target amount and those allowable costs.

(d) *Disclosure of information*—(1) *General rule.* Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section; and

(2) According to § 422.504(d)(1)(iii), CMS has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to CMS under paragraph (b)(2) of this section.

(3) *Restriction on use of information.* Information disclosed or obtained for the purposes of this section may be used by officers, employees, and contractors of DHHS only for the purposes of, and to the extent necessary in, implementing this section.

(e) *Organizational and financial requirements*—(1) *General rule.* Regional MA plans offered by MA organizations must be licensed under State law, or otherwise authorized under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more plans. However, as provided for under this section, MA organizations offering MA regional plans may obtain a temporary waiver of State licensure. In the case of an MA organization that is offering an MA regional plan in an MA region, and is not licensed in each

State in which it offers such an MA regional plan, the following rules apply:

(i) The MA organization must be licensed to bear risk in at least one State of the region.

(ii) For the other States in a region in which the organization is not licensed to bear risk, if it demonstrates to CMS that it has filed the necessary application to meet those requirements, CMS may temporarily waive the licensing requirement with respect to each State for a period of time as CMS determines appropriate for the timely processing of the application by the State or States.

(iii) If the State licensing application or applications are denied, CMS may extend the licensing waiver through the end of the plan year or as CMS determines appropriate to provide for a transition.

(2) *Selection of appropriate State.* In the case of an MA organization to which CMS grants a waiver and that is licensed in more than one State in a region, the MA organization will select one of the States, the rules of which shall apply in States where the organization is not licensed for the period of the waiver.

(f) *Regional stabilization fund*—(1) *Establishment.* The MA Regional Plan Stabilization Fund (referred to in this paragraph (f) as the “Fund”) is available beginning in 2007 for two purposes:

(i) *Plan entry.* To provide incentives to have MA regional plans offered in each MA region under paragraph (f)(4) of this section.

(ii) *Plan retention.* To provide incentives to retain MA regional plans in certain MA regions with below-national-average MA market penetration under paragraph (f)(5) of this section.

(2) *Availability of funding from savings.* Funds made available under section 1853(f) of the Act are transferred into a special account in the Treasury from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f) of the Act, “payments From Trust Funds,” on a monthly basis.

(3) *Funding limitation*—(i) *General rule.* The total amount expended from the Fund as a result of the application of

this section through the end of a calendar year may not exceed the amount available to the Fund as of the first day of that year. For purposes of this section, amounts that are expended under this title insofar as those amounts would not have been expended but for the application of this section will be counted as amounts expended as a result of that application.

(ii) *Application of limitation.* CMS will obligate funds from the Fund for a year only if the Chief Actuary of CMS and the appropriate budget officer certify that there are available in the Fund at the beginning of the year sufficient amounts to cover all of those obligations incurred during the year consistent with paragraph (f)(3)(i) of this section. CMS will take those steps, in connection with computing additional payment amounts under paragraphs (f)(4) and (f)(5) of this section and including limitations on enrollment in MA regional plans receiving those payments or computing lower payment amounts, to ensure that sufficient funds are available to make those payments for the entire year.

(4) *Plan entry funding*—(i) *General rule.* Funding is available under this paragraph for a year in the following situations:

(A) *National plan.* For a national bonus payment described in paragraph (f)(4)(ii) of this section, when a single MA organization offers an MA regional plan in each MA region in the year, but only if there was not a national plan offered in each region in the previous year. Funding under this paragraph is only available with respect to any individual MA organization for a single year, but may be made available to more than one such organization in the same year.

(B) *MA Regional Plans.* Subject to paragraph (f)(4)(i)(C) of this section, for an increased amount under paragraph (f)(4)(iv) of this section for an MA regional plan offered in an MA region that did not have any MA regional plan offered in the prior year.

(C) *Limitation on MA regional plan funding in case of national plan.* There will be no payment adjustment under paragraph (f)(4)(iii) of this section for a year for which a national bonus pay-

ment is made under paragraph (f)(4)(ii) of this section.

(ii) *National bonus payment.* The national bonus payment under this paragraph will—

(A) Be available to an MA organization only if the organization offers MA regional plans in every MA region;

(B) Be available for all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and

(C) Be subject to amounts available under paragraph (f)(3) of this section for a year and be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization.

(iii) *Regional payment adjustment*—(A) *General rule.* The increased amount under this paragraph for an MA regional plan in an MA region for a year must be an amount, determined by CMS, based on the bid submitted for that plan (or plans) and will be available to all MA regional plans offered in that region and year. That amount may be based on the mean, mode, or median or other measure of those bids and may vary from region to region. CMS will not limit the number of plans or bids in a region.

(B) *Multi-year funding.* Subject to amounts available under paragraph (f)(3) of this section, funding will be available for a period determined by CMS.

(C) *Application to all plans in a region.* Funding under this paragraph for an MA region will be made available for all MA regional plans offered in the region.

(D) *Limitation on availability of plan retention funding in next year.* If plans receive plan entry funding in a year, plans in that region are prohibited from receiving plan retention funding in the following year.

(iv) *Application.* Any additional payment under this section provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(5) *Plan retention funding*—(i) *General rule.* Funding is available under this

paragraph for a year with respect to MA regional plans offered in an MA region for the increased amount specified in paragraph (f)(5)(ii) of this section but only if the region meets the requirements of paragraphs (f)(5)(iii)(A), (f)(5)(iii)(B), (f)(5)(iii)(C) and (f)(5)(iii)(E) of this section.

(ii) *Payment increase.* The increased amount under this paragraph for an MA regional plan in an MA region for a year will be an amount, determined by CMS, that does not exceed the greater of—

(A) 3 percent of the benchmark amount applicable in the region; or

(B) The amount as (when added to the benchmark amount applicable to the region) will result in the ratio of—

(I) That additional amount plus the benchmark amount computed under section 1854(b)(4)(B)(i) of the Act, “the risk-adjusted benchmark amount” for the region and year, to the adjusted average per capita cost for the region and year, as estimated by CMS under section 1876(a)(4) of the Act and adjusted as appropriate for the purpose of risk adjustment; being equal to—

(2) The weighted average of those benchmark amounts for all the regions and that year, to the average per capita cost for the United States and that year, as estimated by CMS under section 1876(a)(4) of the Act and adjusted as appropriate for the purpose of risk adjustment.

(iii) *Regional requirements.* The requirements of this paragraph for an MA region for a year are as follows:

(A) *Notification of plan exit.* CMS has received notice (as specified by CMS), before a new contract year, that one or more MA regional plans that were offered in the region in the previous year will not be offered in the succeeding year.

(B) *Regional plans available from fewer than two MA organizations in the region.* CMS determines that if the plans referred to in paragraph (f)(5)(iii)(A) of this section are not offered in the year, fewer than two MA organizations will be offering MA regional plans in the region in the year involved.

(C) *Percentage enrollment in MA regional plans below national average.* For the previous year, CMS determines that the average percentage of MA eli-

gible individuals residing in the region who are enrolled in MA regional plans is less than the average percentage of those individuals in the United States enrolled in those plans.

(D) *Application.* Any additional payment under this paragraph provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(E) *2-consecutive-year limitation.* In no case will plan retention funding be available under this paragraph in an MA region for more than 2 consecutive years.

[70 FR 4732, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

## Subpart K—Contracts With Medicare Advantage Organizations

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

### § 422.500 Scope and definitions.

(a) *Scope.* This subpart sets forth application requirements for entities seeking a contract as a Medicare organization offering an MA plan. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of part 423 of this chapter specifically related to the prescription drug benefit.

(b) *Definitions.* For purposes of this subpart, the following definitions apply:

*Business transaction* means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or